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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,331	07/11/2003	Laurence Du-Thumm	IR 7050-00	5282

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Colgate-Palmolive Company  
909 River Road  
P.O. Box 1343  
Piscataway, NJ 08855-1343

EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/618,331	<b>Applicant(s)</b> DU-THUMM ET AL.	
	<b>Examiner</b> Frederick Krass	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05/24/06 (RCE Filing).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11, 16-18 and 20-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 16-18 and 20-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

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### **Previous Rejections**

Unless specifically repeated infra, all previous rejections are withdrawn.

### **Claim Informalities**

The following informalities are noted and should be corrected in responding to this

Office action:

1) claim 11, third line, the phrase “which is” should be inserted before “incorporated” for grammatical purposes; and

2) claim 16 should be amended to end in a period.

### **Indefiniteness Rejection**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22, first line, “the sugar alcohol” lacks antecedent basis (claim 21 instead recites a “polyol”).

### **Obviousness Rejection**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 11, 16-18, 20-24, 26-42 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gebreselassie et al (USP 6,379,654) in view of Wagenknecht et al (USP 4,148,872).

The primary reference discloses dentifrice compositions containing abrasives, including pastes and gels (column 6, lines 26 and 27), for use in cleaning teeth (column 1, lines 21-29). The compositions contain 0.1 to 10 weight percent (preferably 0.5 to 5 percent) of a proteolytic enzyme such as papain as an active agent (column 3, lines 4-12) and ingredients “which stabilize enzymes in the dentifrice environment”. These ingredients include 0.1 to 1 percent (preferably 0.1 to 0.5 percent) of a metal chelating agent, *e.g.*, EDTA or sodium gluconate, and 0.1 to 1.5 percent (preferably 0.3 to 0.75 percent) of an antioxidant, *e.g.*, sodium bisulfite, metal gallates, sodium stannate and ascorbic acid. See column 5, lines 2-15. The prior art differs from the instant claims insofar as it is silent regarding the use of chewing gum dentifrices.<sup>1</sup>

The secondary reference teaches that the use of chewing gums containing abrasives (column 8, lines 6-14) are preferred to toothpastes for cleaning teeth (column 2, lines 25-49) because the former permit a prolonged period of contact with the oral cavity, which also minimizes the amount of active agent required. See the passage bridging column 3, line 61 to column 4, lines 2. The reference also provides directions for preparing these alternative forms by balancing considerations of duration of action with amount of active agent required. See column 4, lines 3-26. It also teaches various well-known chewing gum formulations and ingredients,

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<sup>1</sup> The examiner believes that the prior art discloses confectionary “tablets” as required by instant claim 32 in its description of various “hard” candies, lozenges and the like at column 3, lines 55-57. In any case, the formulation of chewing gums as tablets is well-known. See, *e.g.*, USP 4,981,698 at column 13, lines 25-27.

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including gum bases in amounts of 10 to 95 percent by weight (see the passage bridging column 6, line 59 to column 7, line 21), artificial sweeteners such as saccharin and cyclamates (column 7, lines 29-33), sugar alcohols such as xylitol, sorbitol and mannitol in amounts of 5 to 80 percent by weight (column 7, lines 33-48), glycerine and/or wax plasticizers in amounts of 0.01 to 10 percent by weight (column 8, lines 33-41, and column 7, lines 6-10), and abrasives including calcium salts such as calcium carbonate (column 8, lines 21-32). The presence of water is optional, and when it is present the disclosed lower limit is 2 percent, well within the range recited by instant claims 28 and 29; see column 8, lines 42-44. See also working example 1 at column 10, wherein a chewing gum containing the noncariogenic sweeteners xylitol and mannitol is prepared; insofar as can be determined the formulary components were mixed at room temperature, thus meeting the limitations of instant claim 30. The secondary reference differs from the instant claims insofar as it is silent regarding the use of enzymes.

It would have been obvious to have formulated the paste dentifrices of the primary reference in the form of chewing gums, motivated by the desire to provide prolonged cleaning activity while lowering the required amount of active agent as taught by the secondary reference.

2) Claims 25 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gebreselassie et al (USP 6,379,654) in view of Wagenknecht et al (USP 4,148,872), the combination being taken further in view of Andersen et al (USP 5,487,902).

The primary and secondary references and the motivation for their combination is provided in subsection "1)" supra. The chewing gums suggested by the combined teachings of the primary and secondary reference differ from those of the instant claims insofar as 1) sugar

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alcohols of disaccharides are not specifically disclosed (instant claim 25) and 2) a specific combination of softeners comprising 0.5 to 3 percent lecithin and 0.1 to 1.0 percent glycerin (instant claim 43) are not specifically set forth.

The tertiary reference is cited to demonstrate the state of the chewing gum art. Among other things, it teaches that sugar alcohols of disaccharides, *e.g.*, palatinit, are known for use as non-cariogenic sweeteners, along with sugar alcohols such as xylitol. See column 11, lines 9-12. Additionally, it teaches that lecithin is a known softener/plasticizer for use in chewing gums, alone with glycerin. See column 11, lines 40-46. And finally, the reference teaches that it is well-known to vary the type and proportions of such ingredients depending on the desired properties of the final chewing gum product. See column 11, lines 47-53. The secondary reference differs from instant claims insofar as, although it mentions enzymes, including papain, at column 10, lines 2-22, and antioxidants such as BHT at column 7, lines 26-30, it does so in the context of a very large “laundry list” of potential active agents and formulary ingredients, such that insufficient guidance is provided for arriving at any particular combination of enzyme and stabilizing agent.

Established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, *e.g.*, In re Linder, 457 F.2d 506, 507 (CCPA 1972); see also In re Dial, 326 F.2d 430, 432 (CCPA 1964). Accordingly, it would have been obvious to have incorporated a sugar alcohol of a disaccharide into the chewing gums suggested by the combined teachings of the primary and secondary references for its art-recognized sweetening function as taught by the tertiary reference, consonant with the reasoning of such precedent.

Similarly, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980); In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960). Accordingly, it would have been obvious, consonant with the reasoning of such precedent, to have used a combination of lecithin and glycerin as a softener in the chewing gums suggested by the combined teachings of the primary and secondary references, since each is known individually as a softener for that same use as taught by the tertiary reference.<sup>2</sup>

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<sup>2</sup> It is similarly generally obvious to determine workable/optimal proportions. See, e.g., In re Aller, 105 USPQ 233, 235 (CCPA 1955); In re Boesch, 205 USPQ 215 (CCPA 1980) and In re Peterson, 315 F.3d 1325 (C.A. Fed 2003). Thus, the corollary selection of the instantly claimed proportions of lecithin and glycerin, where such proportions would have provided optimal results, would also have been obvious as well.



### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached on Monday-Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
Art Unit 1614

